

## Remarks

Claims 1 to 10 and 26 to 32 are pending and under consideration. Claims 11 to 25 are also pending, but have been withdrawn from consideration.

### 35 U.S.C. § 112, first paragraph rejection

The Examiner rejects claims 1 to 9 and 26 to 29 under 35 U.S.C. § 112, first paragraph as allegedly “containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” See Action at page 2. Specifically, the Examiner alleges that the phrase “wherein at least one of the features does not comprise a control-specific probe” does “not have any expressed basis in the original specification.” See *id.*, at pages 2 and 3. The Examiner also cites *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff’d mem.*, 738 F.2d 453 (Fed Cir. 1984). The Examiner states that “[t]he mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.” See *id.* Applicants respectfully traverse.

Applicants assert that there is basis for the phrase “wherein at least one of the features does not comprise a control-specific probe” in the specification. For example, at pages 4 to 5, paragraph 10, the specification states, “***In certain embodiments***, a control label is included in each feature of the array, which provides a control signal that indicates the amount of probe attached” (emphasis added). Here, the use of the term

“in certain embodiments” means that the specification encompasses embodiments that do not include a control label in each feature of the array.

As another example, page 4, paragraph 9, includes the sentence, “***In certain embodiments***, the controls comprise nucleic acid sequence control probes that are included in each feature” (emphasis added). Here, the term “in certain embodiments” means that the specification includes embodiments where the controls comprise nucleic acid sequence control probes that are not included in each feature.

As another example, page 13, paragraph 43, includes the language, “***In all the embodiments in which a control signal is present at a feature***, that control signal can be used to define the shape of the feature” (emphasis added). The phrase “in all the embodiments in which a control signal is present at a feature” indicates that there are embodiments in which a control signal is not present at a feature.

Any one of the above statements is sufficient support for the claim language “wherein at least one of the features does not comprise a control-specific probe.” But the specification is not limited to a single statement for support. As shown above, language in the specification repeatedly conveys embodiments wherein at least one of the features does not comprise a control-specific probe. Additionally, the cumulative effect of all of the above statements should make clear that the specification includes embodiments “wherein at least one of the features does not comprise a control-specific probe.”

Furthermore, the reasoning of the case cited by the Examiner, *Ex parte Grasselli*, does not apply to the claims in this application. In *Grasselli*, the applicants claimed a process for ammoxidation of propane or isobutane in the absence of certain elements,

where the absence of those elements was not disclosed in the specification. The court stated that “the negative limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. § 112.” See *Grasselli* at page 394. That reasoning for a § 35 U.S.C. § 112, first paragraph, rejection does not apply to the claims of this application. Specifically, the claims currently rejected by the Examiner introduce no new concepts. The applicants are merely claiming less than they are entitled to claim from the specification.

In fact, the Board considered *Grasselli* and the issue of negative elements in *Ex parte Parks*, 30 USPQ2d 1234 (Bd. App. 1993). In *Parks*, the Board stated, “Adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. [citation omitted] Rather it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed. [citation omitted]” See *Parks* at page 1236. Here, the originally-filed disclosure would have conveyed to one having ordinary skill in the art that the applicants had possession of the claimed concept. As shown above, one skilled in the art would understand that language throughout the specification conveys embodiments in which one of the features does not comprise a control-specific probe. Literal support for the added language is not required. All that is required is that the specification convey to one having ordinary skill in the art that applicants had possession of the claimed concept. That standard is satisfied for the rejected claims.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 to 9 and 26 to 29 under 35 U.S.C. § 112, first paragraph.

### **Rejection in View of Brink and McMillan**

The Examiner rejected claims 1 to 10 and 26 to 32 under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,563,034 ("Brink"), in view of U.S. Patent No. 6,312,929 ("McMillan"). See Action, page 3. Applicants respectfully traverse.

### **Independent Claims 1, 27, 31, and 32**

The Examiner alleges that Brink teaches a method comprising "exposing a substrate containing a first feature comprising an experimental target-specific probe and a control-specific probe to a labeled control target." See Action, page 3. The Examiner cites claim 1 and Col. 9, lines 15 to 32, of Brink for this aspect of claim 1. See *id.*

As applicants pointed out in the Amendment filed on November 20, 2003, the cited portions of Brink do not discuss "exposing a substrate containing a first feature comprising an experimental target-specific probe and a control-specific probe to a labeled control target." Claim 1 of Brink discusses "contacting an aliquot of the sample with an oligo-nucleotide probe" and "contacting an equivalent aliquot of the sample with a labeled nucleic acid negative control probe." See Brink, claim 1. Thus, claim 1 of Brink discusses parallel assays. It does not discuss "exposing a substrate containing a first feature comprising an experimental target-specific probe and a control-specific probe to a labeled control target." The other portion of Brink cited by the Examiner, Col. 9, lines 15 to 32, discusses fixing targets to nitrocellulose and probing them with DNA

probes. However, it does not discuss a control-specific probe. Thus, Brink does not teach “exposing a substrate containing a first feature comprising an experimental target-specific probe and a control-specific probe to a labeled control target.”

Furthermore, even if the Examiner combines the two cited sections, Brink still fails to teach “exposing a substrate containing a first feature comprising an experimental target-specific probe and a control-specific probe to a labeled control target.”

Specifically, Brink teaches separate but parallel assays. One assay uses target-specific probe. The parallel assay uses negative control probe. In fact, Brink states that the function of the reverse polarity oligonucleotides “is to serve as negative control probes *in parallel assays with the target-specific probe*, to discriminate true positives from background signal.” See Brink, Col. 8, lines 1 to 3 (emphases added).

Thus, where Brink discusses the use of targets attached to nitrocellulose, the targets for the negative control probe and the targets for the target-specific probe are attached to different areas. Furthermore, the Examiner has failed to point to any of the rest of the disclosure of Brink that would suggest negative control probe and target-specific probe operating in the same assay. In fact, Brink does not discuss how to distinguish the signal of the negative control probes from the signal of the target-specific probes. Thus, the Examiner failed to establish that Brink discloses “exposing a substrate containing a first feature comprising an experimental target-specific probe and a control-specific probe to a labeled control target.”

McMillan fails to remedy the deficiencies of Brink. Accordingly, for at least this reason, the Examiner has failed to establish that claims 1, 27, 31, and 32 would have been obvious over Brink in view of McMillan. Claims 2 to 9, 28, and 29 depend from

either claim 1 or claim 27. Thus, for the reasons discussed above for claims 1 and 27, the Examiner fails to establish that claims 2 to 9, 28, and 29 would have been obvious over Brink in view of McMillan. Because the Examiner fails to establish that claims 1 to 9, 27 to 29, 31, and 32, would have been obvious for at least the reasons discussed above, applicants need not address the Examiner's contentions concerning other elements of those claims. By not addressing those contentions, applicants in no way acquiesce to those contentions.

Applicants respectfully request reconsideration and withdrawal of the § 103 rejection over Brink in view of McMillan.

#### **Independent Claims 10 and 30**

The Examiner rejected claims 10 and 30 under 35 U.S.C. § 103(a) as allegedly being obvious over Brink, in view of McMillan. See Action, page 3. The Examiner acknowledged that Brink “does not teach a method, wherein there is a labeled experimental target and wherein the labeled control target competes with the labeled experimental target for binding to the experimental target probe.” See *id.*, page 7. The Examiner alleges that “McMillan teaches a method, wherein there is a labeled experimental target and wherein the labeled control target competes with the labeled experimental target for binding to the experimental target probe...” See *id.*, at page 7. The Examiner then cites to particular sections of McMillan to attempt to support that allegation. See *id.* Applicants respectfully traverse.

Applicants respectfully assert that the cited sections of McMillan fail to disclose or suggest the claim language “wherein the labeled control target competes with the

labeled experimental target for binding to the experimental target probe” (claim 10).

Similarly, applicants respectfully assert that the cited sections of McMillan fail to disclose or suggest the claim language “wherein the synthetic control target sequences compete with the experimental target sequences for binding of the experimental probes” (claim 30).

The Examiner presumably chose the cited sections of McMillan for the discussion in those sections concerning target probe (HP1) and second control probe (HP3) binding to the second control template (IC2). See McMillan at Figure 1, at col. 5, line 36 to col. 6, line 63, at col. 12, line 66 to col. 13, line 30, at Table 1, and at Example. However, those sections do not disclose a target probe (HP1) and a second control probe (HP3) that compete for binding to the same second control template (IC2). Specifically, the cited sections of McMillan discuss second control template (IC2), which comprises both a target probe (HP1) hybridization region and second control probe (HP3) hybridization region. See *id.* Thus, both the target probe (HP1) and second control probe (HP3) bind to the second control template (IC2) at the same time without competing with one another. See *id.* In fact, all of the sections that the Examiner cites show that the second control probe (HP3) hybridizes to a separate region of the second control template (IC2) than the target probe (HP1). See, e.g., McMillan at Figure 1.

Thus, McMillan does not disclose the language “wherein there is a labeled experimental target and wherein the labeled control target competes with the labeled experimental target for binding to the experimental target probe.”

For at least this reason, the Examiner has failed to establish that Brink in view of McMillan shows all of the elements of independent claims 10 and 30. Thus, applicants

need not address the Examiner's contentions concerning the other elements of those claims. By not addressing those contentions, applicants in no way acquiesce to those contentions.

Applicants respectfully request reconsideration and withdrawal of the § 103 rejection of claims 10 and 30 in view of Brink and McMillan.

### **Claim 26**

Claim 26 contains the language, "wherein the array comprises **three** or more features, and wherein at least one of the features does not comprise a control-specific probe" (emphasis added). The Examiner did not address that aspect of claim 26 in the Action. However, the Examiner did address the language "wherein the substrate contains two or more features; and wherein at least one of the features does not comprise a control-specific probe", which is included in certain other claims. The Examiner alleges that McMillan shows that aspect of those claims by citing McMillan's discussion of controls for PCR that appears at Figure 1, col. 5, line 36 to col. 6, line 63, col. 12, line 66 to col. 13, line 30, and claims 1 to 12. See Action, page 7.

The cited sections of McMillan, however, do not disclose a method, "wherein the substrate contains two or more features; and wherein at least one of the features does not comprise a control-specific probe." Nor do they disclose a method, "wherein the array comprises three or more features, and wherein at least one of the features does not comprise a control-specific probe." In fact, those sections of McMillan discuss the use of controls for PCR reactions. In McMillan, all of the control probes, templates, and primers are in a single reaction composition. For example, claim 1 of McMillan states,



“A method of performing ***an amplification reaction***, comprising: (a) ***combining in an aqueous solution*** (i) a target probe, a first control probe and a second control probe...” (emphasis added). Therefore, all three probes are combined in a single aqueous solution. Thus, even if the amplification reaction is somehow improperly construed as a feature, both control probes and the target probe will be in the same feature.

Therefore, McMillan does not disclose a method “wherein the array comprises three or more features, and wherein at least one of the features does not comprise a control-specific probe.”

For at least this reason, the Examiner has failed to establish that Brink in view of McMillan would have rendered obvious independent claim 26. Thus, applicants need not address the Examiner’s contentions concerning the other elements of that claim. By not addressing those contentions, applicants in no way acquiesce to those contentions.

Applicants respectfully request reconsideration and withdrawal of the § 103 rejection of claim 26 in view of Brink and McMillan.

### **Conclusion**


Applicants respectfully assert that the application is in condition for allowance and request issuance of a Notice of Allowance. If the Examiner does not consider the application to be in condition for allowance, applicants request that he call the undersigned at (650) 849-6620 to set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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By:  Reg No.  
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